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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/936,668	6,668 09/13/2001		Jack Thacher Leonard	MCA-448 PC/US	8911
25 (82	7590	03/22/2005	EXAMINER		INER
MILLIPOR			MENON, KR	MENON, KRISHNAN S	
290 CONCORD ROAD BILLERICA, MA 01821				ART UNIT	PAPER NUMBER
				1723	
				DATE MAILED: 03/22/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

			<i>W</i>				
		Application No.	Applicant(s)				
		09/936,668	LEONARD, JACK THACHER				
	Office Action Summary	Examiner	Art Unit				
		Krishnan S Menon	1723				
Period fo	The MAILING DATE of this communication Reply	on appears on the cover sheet wil	th the correspondence address				
THE I - External after - If the - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR F MAILING DATE OF THIS COMMUNICAT asions of time may be available under the provisions of 37 C SIX (6) MONTHS from the mailing date of this communicati period for reply specified above is less than thirty (30) days period for reply is specified above, the maximum statutory or to reply within the set or extended period for reply will, by reply received by the Office later than three months after the red patent term adjustment. See 37 CFR 1.704(b).	ION. CFR 1.136(a). In no event, however, may a re- ion. s, a reply within the statutory minimum of thirty period will apply and will expire SIX (6) MON' statute, cause the application to become AB.	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed on	22 February 2005.					
	<u> </u>	This action is non-final.					
3)□	_						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	ion of Claims						
5)⊠ 6)⊠ 7)□	Claim(s) <u>1-6,8,10-20,22-28,30 and 32-34</u> 4a) Of the above claim(s) is/are with Claim(s) <u>2,4,6,11-14,16,18 and 22</u> is/are Claim(s) <u>1,3,5,8,10,15,17,19,20,23-28,30</u> Claim(s) is/are objected to. Claim(s) are subject to restriction is	thdrawn from consideration. allowed. O and 32-34 is/are rejected.	n.				
Applicati	on Papers						
9)□	The specification is objected to by the Exa	aminer.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)	Replacement drawing sheet(s) including the cathe oath or declaration is objected to by the cathering	•	` ' '				
Priority ι	ınder 35 U.S.C. § 119						
a)[Acknowledgment is made of a claim for for All b) Some * c) None of: 1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International Beet the attached detailed Office action for	aments have been received. Iments have been received in Ape priority documents have been Bureau (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachment	t(s)						
	e of References Cited (PTO-892)		ummary (PTO-413))/Mail Date				
3) 🔲 Inform	e of Draftsperson's Patent Drawing Review (PTO-94 nation Disclosure Statement(s) (PTO-1449 or PTO/5 r No(s)/Mail Date		formal Patent Application (PTO-152)				

DETAILED ACTION

Claims 1-6,8,10-20,22-28,30 and 32-34 are pending after the RCE of 2/22/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 8, 10, 15, 17, 19-20, 23-24, 27-28 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,223,133 (hereinafter referred to as Clark et al '133).

Clark et al '133 teach a process for concentration of nucleic acids comprising the steps of providing ultrafiltration membrane (15) having a molecular cutoff between 1 00 D and 2000 kD and made of polysulfone in 25 multiple wells (11), processing a volume of up to 400 microliters i.e. 0 to 400 microliters of sample, subjecting the sample on the membrane to vacuum (5) till nucleic acids are concentrated on the membrane (see figures 1-3, 6-7; col. 3, lines 15-18; col. 3, line 60 – col. 4, line 36; col. 5, lines 28-61). The filtration is at constant pressure, since the vacuum applied is a regulated external vacuum source (see col. 3, line 60 - col. 4, line 11), which does not vary during filtration.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 3, 25-26, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,223,133 (Clark et al; hereinafter referred to as Clark).

Clark et al '133 teach a process for concentration of nucleic acids comprising the steps of providing ultrafiltration membrane (15) having a molecular cutoff between 1 00 D and 2000 kD and made of polysulfone in 25 multiple wells (11), processing a volume of up to 400 microliters i.e. 0 to 400 microliters of sample, subjecting the sample on the membrane to vacuum (5) till nucleic acids are concentrated on the membrane (see figures 1-3, 6-7; col. 3, lines 15-18; col. 3, line 60 – col. 4, line 36; col. 5, lines 28-61).

Regarding claims 3, 25-26, and 30, regulating the pressure differential to 169-914 millibars would be only optimizing the vacuum/pressure differential required for the filtration conditions. Clark teaches a regulated vacuum supply. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

No. 5,223,133 (Clark et al; hereinafter referred to as Clark) in view of U.S. Patent

No. 5,266,495 (hereinafter referred to as Lapidus).

Clark teaches all the limitations of claim 1. Instant claim adds the further limitation of a positive pressure of 5-80 psi, which Clark does not teach. Lapidus teaches constant positive pressure filtration (see figures and col 2 lines 56-66). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Lapidus in the teaching of Clark because Lapidus provides a method for controlled instrumented processing and quantitative information of the parameters during the filtration process (see col 1 lines 15-30).

Allowable Subject Matter

Claims 2, 4, 6, 11-14, 16, 18 and 22 are allowed.

Response to Arguments

Applicant's arguments filed 2/22/05 have been fully considered but are moot regarding the rejected claims because of the new grounds for rejection.

Conclusion

This action follows an RCE and is made non-final due to the grounds for rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan Menon Patent Examiner

> W. L. WALKER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1700